EDITORIAL

Consent bias in research: how to avoid it

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See article on page 1116

Consent bias, also known as authorisation bias or volunteer bias, is described as a systematic error in creating patient groups, such that they differ with respect to study outcome. That is, the groups differ in measured or unmeasured baseline characteristics because of the way participants were selected or assigned. It is also used to mean that the participants are not representative of all possible participants.[1] In short, it describes the impact on a study when those who consent to participate in research differ from those who do not or cannot consent. Buckley *et al*[2] in the current edition of *Heart* (***see article on page 1116***) add to the small but important body of evidence showing how ethical requirements can bias medical research in the area of cardiovascular disease in a large community-based cohort.[3 4]

WHY IS CONSENT BIAS IMPORTANT?

Why is consent bias important for researchers and clinicians? In a review Hewison and Haines noted that consent requirements for recruiting patients to medical research could result in a failure to include participants who were most likely to benefit from interventions, such as older or socioeconomically deprived patients.[5] It might lead to under- or overestimation of incidence or prevalence of a condition, it might bias assessment of an association between risk factors and health outcome, fail to detect differences in quality of care between certain patient groups and fail to capture the full range of views about a health concern. Biased research ultimately leads to poorer patient care, as evidence may be unreliable or invalid (low response rate), misleading (failure to capture an important association owing to selection bias) or lacking (failure to start or complete research projects owing to prohibitive costs and administrative burden).

Although scientific evidence on the effects of consent requirements is growing, there has been surprisingly little research into patients' views on this issue. Ethical review boards often enforce the opt-in approach with the patients' interest at heart. Whereas there is a suggestion that an opt-in approach is what patients prefer[6] or expect,[7] there is no evidence that patients would chose improved confidentiality over improved health, if asked to make a cost–benefit trade-off between poor medical research and the risk of intrusion of privacy. Non-response is more likely to be due to apathy[8] or misconception[9] than to principled objection. Few patients deny consent,[8] or object,[10] when contacted directly, and even fewer complain about being approached for research.[8]

WHAT CAN RESEARCHERS DO ABOUT CONSENT BIAS?

One way to deal with consent bias, in an environment where opt-out is no longer considered an ethical option, is to adjust for it using an anonymised sample of the full patient data.[11] However, this is no panacea. Although the proposed method may detect bias and adjust for it, it is also clear that no amount of statistical manipulation can remedy poor data. In addition, even obtaining anonymised data represents hurdles and the process is likely to add to the recognised substantial time-intensive and costly burden of ethics and governance requirements.[12]

An alternative solution for UK researchers would be an application to the Patient Information Advisory Group (PIAG) provision under the Health and Social Care Act (2001). This body can give permission to use data without patient consent, where the effort to obtain consent is impractical and it can be proved that a low response rate would compromise the validity of the research. Application to the PIAG, however, is still a lengthy process and what constitutes compromised research or a disproportionate effort to obtain consent is open to interpretation.

Another plausible solution would be explicitly to ask the ethics review board to consider the opt-out approach as default when submitting an ethics application and draw on published research as evidence in favour of the opt-out approach.[3] The patients' right to opt out of their data being used is safeguarded and patients who would not be able to opt out owing to mental ill health or terminal illness would be protected by their doctors from being approached for research.[5]

WHAT CAN ETHICS REVIEW BODIES DO ABOUT CONSENT BIAS?

It is the interpretation of the law by guardians and review bodies rather than the law (Common Law of Confidentiality, the Data Protection Act 1998 and the Human rights Act 1998) itself which unnecessarily hinders important medical research, as some ethics committees find opting-out of patient recruitment acceptable.[13] In the light of observed variability in decision making, a recent report issued by the Academy of Medical Sciences called for a clearer framework on these issues.[14] In addition to considering opt-out as the default, an explicit assessment of risks and benefits has been proposed, which might help sensible, more standardised decisions for each individual study to be reached.[15]

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Box 1: Checklist to look for effects of consent bias

- Are the total numbers in the study approached for consent reported? If not, it is difficult to gauge how representative this paper is of your patient population—treat with caution.
- Is the consent method documented?
  - Is it opt-in or active consent (more likely to lead to bias)
  - or opt-out or passive consent (less likely to lead to bias).
- Is the percentage response/consent rate reported? A response rate of at least 60% is common in community cohorts, whereas it is expected to be higher for hospital-based cohorts. A low response rate may lead to diminished validity for your patient population.
- If the study used an opt-in approach:
  - Have comparisons or adjustments been made to ensure generalisability?
  - Do the authors report the impact of their approach on generalisability or validity on their study?
- Are the baseline characteristics of the patients in the study broadly similar to your patient population?

WHAT CAN CLINICIANS DO ABOUT CONSENT BIAS?

It is important that clinicians and patients as ''end users'' of research can spot consent bias and draw appropriate conclusions. In addition to critically appraising each paper, we propose a checklist to look for effects of consent or authorisation bias (box 1).

CONCLUSION

Consent bias has potentially serious consequences for the quality of medical research, the use of public resources and the quality of patient care. A public debate on the benefits and harms of being approached for medical research is important but has not yet happened. As Buckley *et al* argue in their paper, there is a public lack of knowledge about research, and education about research was shown to increase patients' willingness to participate in research.[16] Possibly, the public may decide that individual privacy is more important than the societal benefits of research, once an open debate has taken place. In this case, patient education may be the only way forward to ensure adequate and unbiased participation in research. Until that debate, however, we need more fearless ethics committees, more critical doctors, more assertive researchers and rigorous data security.

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